

JUN 16 2011

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Section 5: 510(k) Summary

Trade Name: GuardaCare™XR
Common Name: Wound Dressing
Classification Name: Dressing
Product Code: FRO/KMF
Predicate Device(s): mRDH Bandage - K082703

Company Name: HemCon Medical Technologies, Inc.
Company Address: 10575 SW Cascade Avenue, Suite 130
Portland, OR 97223

Contact Person: Kevin Hawkins
Director – Quality & Regulatory
Contact Phone: (503)245.0459 x114
Contact Fax: (503)245.1326

Date of Preparation: 10 June 2011

Description of the Device:

The GuardaCare™XR dressing is composed of a radiopaque element attached to standard polyester/rayon blend non-woven medical gauze that is coated with chitosan. The product is produced in multiple sizes; e.g. two (2) inches by two (2) inches, eight-ply; four (4) inches by four (4) inches, eight-ply; and four (4) inches by two (2) yards (z-folded 4"x4"). All sizes are a single continuous length that is z-folded to the appropriate size. The products are double-pouched. The inner pouch is peelable foil and the outer pouch is clear peelable polyethylene terephthalate (PET). The pouched dressings are terminally sterilized with gamma irradiation to a sterility assurance level (SAL) of 10^{-6} .

The hemostatic properties of chitosan enhance the ability of the medical gauze to control bleeding. The radiopaque element allows for easy detection via x-ray to prevent the dressing from being inadvertently left in a surgical cavity.

Intended Use:

GuardaCare™XR is a hemostatic dressing intended for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Technological Characteristics:

GuardaCare™XR is technologically similar to the predicate device. The mRDH dressing has demonstrated the safety and efficacy of a poly-N-acetylglucosamine based dressing for use in surgical procedures. It also has demonstrated the safety and efficacy of a gauze product with an integrated radiopaque element. GuardaCare™XR is a poly-N-acetylglucosamine-based hemostatic with an x-ray detectable feature. It is therefore technologically similar to the mRDH dressing.

Non-Clinical Performance Data:Biocompatibility

Biocompatibility has been demonstrated per ISO 10993.

In Vivo Efficacy

Two separate in vivo studies were designed and conducted to establish the hemostatic efficacy of the product in different injury types that were created to represent the likely use of the different product sizes. In both studies the device was tested side-by-side against a competitive hemostatic dressing. The first study tested the ability of the 4 inch by 4 yard size to control bleeding in 6mm femoral perforation injury in a swine. The second study measured the ability of a two inch by two inch 8-ply size to control bleeding in a splenic capsular strip injury in a swine. In both cases, the device proved to successfully control bleeding at least as well as the competitive product used as a reference.

Sterility

A sterility validation for GuardaCare™XR was completed following ISO 11137:2006 requirements to demonstrate a 10^{-6} SAL using the VD_{max}^{25} method.

Radiopacity:

The radiopacity of GuardaCareXR was determined via testing performed in accordance with ASTM F640-07 Method C (Standard Test Methods for Determining the Radiopacity for Medical Use). The product was found to be equivalent to the radiopacity of the ASTM Radiopacity Standard (101x76x0.9 millimeter 99+% 1100 alloy aluminum sheet) and was therefore determined to be acceptable.

Clinical Performance Data:

Based upon the substantial equivalence determination for the predicate device, no clinical data is required for evaluation of this device.

Substantial Equivalence:

The conclusion drawn from the technological characteristics and non-clinical performance data is that the device is as safe and effective as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

HemCon Medical Technologies, Inc.
% Mr. Kevin Hawkins
VP, Quality & Regulatory Affairs
10575 SW Cascade Avenue, Suite 130
Portland, Oregon 97223-4363

JUN 16 2011

Re: K103641

Trade/Device Name: GuardaCare™ XR
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 13, 2011
Received: June 14, 2011

Dear Mr. Hawkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

Applicant: HemCon Medical Technologies, Inc.

510(k) Number: K103641

Device Name: GuardaCare™XR

Indications for Use:

HemCon GuardaCare™XR is a hemostatic dressing intended for the temporary control of severely bleeding wounds such as surgical wounds and traumatic injuries.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(Please Do Not Write Below This Line - Continue On Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103641